REMARKS

This paper is supplemental to the Amendment under 37 CFR § 1.116 filed September 10, 2004, which applicant understands has been entered into the file.

Claims 1-3, 6, 8-9, 13, and 15-36 are pending in the application and stand variously rejected. By way of this amendment, certain claims have been changed. The markings to the claims shown above reflect changes to the claims as they were presented in the September 10 Amendment. No claim has been added since the last Office Action.

The amendments to the claims are supported by the claims as previously presented, and throughout the specification. Use of a medium conditioned by fibroblast feeder cells is illustrated at several places in the specification, such as Example 1 (page 29 ff.) and Example 6 (page 37 ff.). The claims maintain coverage for equivalents of the fibroblast feeder cells and the conditioned medium to the extent permitted under the Doctrine of Equivalents.

Further consideration and allowance of the application is respectfully requested.

Interview Summary:

The undersigned wishes to express his gratitude to Examiner Thái-An N. Ton and Examiner Joseph Woitach for the helpful interview regarding this application held at the Patent Office on March 1, 2005. Possible amendments to the claims were discussed. This paper incorporates amendments and remarks presented during the interview.

Rejections under 35 USC § 112 ¶ 1:

The pending claims stand rejected under the enablement requirement of § 112 ¶ 1. The Office Action indicates that the specification is enabling for methods of obtaining or producing genetically altered hES cells in the absence of feeder cells on an extracellular matrix in a medium conditioned by feeder cells.

The claims are herein amended as recommended by the Examiners. The cells are explicitly involve culturing the hES cells *on an extracellular matrix in a medium conditioned by fibroblast feeder cells.*

Accordingly the rejection made in the previous Office Action is moot. Applicant maintains that the application as filed is enabling for further methods of making genetically modified cells, coverage for which will be pursued in a related application.

Claims 17-21 relate to hES cells differentiated into populations of neurons or hepatocytes. The present application as filed describes a method for differentiating hES cells into populations comprising over 90% neural cells (page 20, lines 18-31). This is an embodiment of the method described in U.S. Patent 6,833,269 and its priority application, filed May 17, 2000. The present application as filed also describes a method for differentiating hES cells into populations comprising over 80% hepatocyte lineage cells (page 20, line32 to page 21, line 2). This is an embodiment of the method described in U.S. Patent 6,458,589 and its priority application, filed April 27, 2000.

Withdrawal of the rejection under § 112 ¶ 1 is respectfully requested.

Double Patenting

Certain claims in this application stand rejected for obviousness type double patenting over claims 62 and 63 of USSN 09/530,346. This application has since been issued as U.S. Patent 6,800,480. The corresponding claims in the issued patent are claims 10 and 11.

The reason given for this rejection in the January 14, 2004 Office Action is that the method claims in the present application are the only way of making the genetically altered cells in the 6,800,480 patent.

Applicants respectfully submit that this rejection is also moot in view of the amendments to the claims made before and herein. The 6,800,480 patent does not explicitly claim genetically altered cells cultured on an extracellular matrix in a medium cultured by fibroblast feeder cells. There are certainly other ways of making genetically altered pPS cells. For example:

- hES cells can be transfected with such agents as Lipofectamine 2000™ and FuGene™ while being cultured on a feeder layer of normal primary mouse fibroblasts. This is illustrated in the specification in Example 3.
- hES cells can be grown on a layer of feeder cells made to be drug resistant, genetically altered, and then selected using the corresponding antibiotic. This is exemplified in the specification in Example 5, and previously presented in claim 4, which has since been cancelled.
- hES cells can also be genetically altered in other feeder-free culture systems. For example, US 2003/0017589 A1 describes a feeder-free system using non-conditioned medium, and its use for making genetically altered cells.

Since the genetically altered cells in the 6,800,480 patent can be made by methods other than those in the claims as presented above, the claims are not obvious over the claims in the issued patent. Accordingly, no Terminal Disclaimer is needed

The application is believed to be in condition for allowance, which is respectfully requested. Should the Examiner determines that there are other matters to be addressed, applicant hereby requests a further interview by telephone.

Fees Due

Accompanying this Amendment are papers authorizing the Commissioner to charge the fee for the extension of time to applicant's deposit account.

Should the Patent Office determine that an extension of time or any other relief is required for further consideration of this application, applicant hereby petitions for such relief, and authorizes the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,

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Facsimile Transmittal Sheet

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